Part 3: Pancreas Transplant Program

Table 1: OPTN Staffing Report

| OPTN Member Code: | Name of Hospital: | |
|-------------------------------|--------------------------|---------------------------------|
| Main Program Phone Number: | Main Program Fax Number: | Hospital URL: <u>http://www</u> |
| Toll Free Phone Numbers for I | Patients: | Hospital #: |

Refer to the staffing audit sent with this application and complete the table below for staff that are not captured on the staffing audit or to update information for current staff, including deleting (DEL) an individual. If you did not receive an audit with this application, complete the entire staffing report. Make sure to use individuals' full, legal names (middle name/initial also included when possible) to prevent duplicate entries within the UNOS Membership Database and UNet.

Identify the transplant program medical and surgical director(s).

| DEL | Name | Address | Phone | Fax | Email |
|-----|------|---------|-------|-----|-------|
| | | | | | |
| | | | | | |

Identify **primary surgeon and additional surgeons** who perform transplants for the program.

| DEL | Name | Address | Phone | Fax | Email |
|-----|------|---------|-------|-----|-------|
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Identify **other surgeons** who perform transplants for the program.

| DEL | Name | Address | Phone | Fax | Email |
|-----|------|---------|-------|-----|-------|
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Identify primary physicians and additional physicians who perform transplants for the program.

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| DEL | Name | Address | Phone | Fax | Email |
|-----|------|---------|-------|-----|-------|
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Identify **other physicians** who perform transplants for the program.

| | DEL | Name | Address | Phone | Fax | Email |
|---|-----|------|---------|-------|-----|-------|
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Identify the **transplant program administrator(s)/hospital administrative director(s)/manager(s)** who will be involved with this program. The * denotes the primary transplant administrator.

| DEL | Name | Address | Phone | Fax | Email |
|-----|------|---------|-------|-----|-------|
| | * | | | | |
| | | | | | |

Identify the **clinical transplant coordinator(s)** who will be involved with this program.

| DEL | Name | Address | Phone | Fax | Email |
|-----|------|---------|-------|-----|-------|
| | | | | | |
| | | | | | |

Identify the **data coordinator(s)** who will be involved in this transplant program. The * denotes the primary data coordinator.

| DEL | Name | Address | Phone | Fax | Email |
|-----|------|---------|-------|-----|-------|
| | * | | | | |
| | | | | | |

Identify the **social worker(s)** who will be involved with this program.

| DEL | Name | Address | Phone | Fax | Email |
|-----|------|---------|-------|-----|-------|
| | | | | | |
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Identify the **pharmacist(s)** who will be involved with this program.

| DEL | Name | Address | Phone | Fax | Email |
|-----|------|---------|-------|-----|-------|
| | | | | | |
| | | | | | |

Identify the **anesthesiologist(s)** who will be involved with this program. The * denotes the director of anesthesiology.

| DEL | Name | Address | Phone | Fax | Email |
|-----|------|---------|-------|-----|-------|
| | * | | | | |
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Identify the **financial counselor(s)** who will be involved with this program.

| | DEL | Name | Address | Phone | Fax | Email |
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Identify the **QAPI team member(s)** who will be involved with this program.

| DEL | Name | Address | Phone | Fax | Email |
|-----|------|---------|-------|-----|-------|
| | | | | | |
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Identify **any other transplant staff** who will be involved with this program.

| DEL | Name | Title | Address | Phone | Fax | Email |
|-----|------|-------|---------|-------|-----|-------|
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Part 3A: Personnel - Transplant Program Director(s)

Identify the surgical and/or medical director(s) of the pancreas transplant program and submit a C.V. for each program director. Briefly describe the leadership responsibilities for each individual.

| Name | Date of Appointmen t | Primary Areas of Responsibility |
|------|----------------------------|---------------------------------|
| | | |
| | | |

Part 3B, Section 1: Personnel - Surgical - Primary Surgeon

1. Identify the primary transplant surgeon:

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital: Date assumed role of primary surgeon:

b) Does the surgeon have FULL privileges at this hospital? (check one)

| Yes | |
|-----|--|
| No | |

If the surgeon does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY): Explain the individual's current credentialing status, including any limitations on practice:

c) How much of the surgeon's professional time is spent on site at this hospital?

Percentage of professional time on site: Number of hours per week:

d) How much of the surgeon's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

| Facility Name | Туре | Location (City, State) | % Professional Time On Site |
|---------------|------|---------------------------|--------------------------------|
| | | | |

e) List the surgeon's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the surgeon has been recertified, use that date. Provide a copy of certification(s). If the surgeon does not have current American or Canadian board certification, provide letters of recommendation requesting this exception and provide the plan for continuing education as described in the OPTN Bylaws.

| Board Certification Type | Certification Effective Date/ Recertificatio n Date (MM/DD/YY) | Certification Valid Through Date (MM/DD/YY) | Certificate Number |
|-----------------------------|---|--|--------------------|
| | | | |

f) Check the applicable pathway through which the surgeon will be proposed. Refer to the OPTN Bylaws for the necessary qualifications and more specific descriptions of the required supporting documents.

| Membership Criteria | | | | |
|---------------------------------------|--|--|--|--|
| 2-Year Transplant Fellowship | | | | |
| Clinical Experience (Post Fellowship) | | | | |
| Pediatric Pathway | | | | |

g) Transplant Experience (Post Fellowship)/Training (Fellowship):

List the name(s) of the transplant hospital(s), applicable dates, program director name(s), and the number of transplants and procurements performed by the surgeon at each transplant hospital.

| Training and Experienc | ASTS Approved Program? Y/N | Approved (MM/DD/YY) | | Progra | Progra | # PA Transplant | # PA Transplan | # of PA Procuremen ts as |
|-----------------------------------|-------------------------------------|---------------------|-----|------------------------|---------------|--------------------|--------------------------|---|
| e | | Start | End | Transplant Hospital | m Director | s as Primary | ts as First Assistant | Primary or 1 st Assistant |
| Fellowship Training | | | | | | | | |
| Experienc e Post Fellowship | | | | | | | | |

h) Describe in detail the proposed primary surgeon's level of involvement in **this** transplant program as well as **prior** training and experience.

| | Describe Level of Involvement in <u>This</u> Transplant Program | Describe Prior Training/Experience |
|---|--|------------------------------------|
| Pre-Operative Patient | | |
| Management | | |
| (Patients with | | |
| Diabetes Mellitus) | | |
| Recipient Selection | | |
| Donor Selection | | |
| Histocompatibility and Tissue Typing | | |
| Transplant Surgery | | |
| Immediate Post- | | |
| Operative and | | |
| Continuing Inpatient | | |
| Care | | |
| Post-Operative | | |
| Immunosuppressive | | |
| Therapy | | |
| Differential Diagnosis | | |
| of Pancreatic | | |
| Dysfunction in the | | |
| Allograft Recipient | | |
| Histologic | | |
| Interpretation of | | |
| Allograft Biopsies | | |
| Interpretation of | | |
| Ancillary Tests for | | |
| Pancreatic | | |
| Dysfunction | | |
| Long-Term | | |
| Outpatient Follow-Up | | |
| Pediatric (if | | |
| applicable) | | |
| Coverage of Multiple | | |
| Transplant Hospitals | | |
| (if applicable) | | |

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| Additional Information: | |
|----------------------------|--|
| | |

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Table 2: Primary Surgeon - Transplant Log (Sample)

Complete a separate form for each transplant hospital.

| Organ: | |
|--|--|
| Name of proposed primary surgeon: | |
| Name of hospital where transplants were performed: | |
| Date range of surgeon's appointment/training: MM/DD/YY to MM/DD/YY | |

List cases in date order. Add rows as needed. Patient ID should <u>not</u> be name or Social Security <i>Number.

| | Date of | Medical Record/ | | |
|--------|------------|--------------------------|-----------------|---------------------------|
| # | Transplant | OPTN Patient ID # | Primary Surgeon | 1 st Assistant |
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| Director's Signature | Date |
|----------------------|------|
| Print Name | |

Table 3: Primary Surgeon - Procurement Log (Sample)

| Organ: | |
|---|--|
| Name of proposed primary surgeon: | |
| Name of hospital where surgeon was employed when procurements were performed: | |
| Date range of surgeon's appointment/training: MM/DD/YY to MM/DD/YY | |

List cases in date order. Add rows as needed. Patient ID should <u>not</u> be name or Social Security <i>Number.

| | Date of | Donor ID | Comments |
|--------|-------------|----------|----------------------|
| # | Procurement | Number | (LD/CAD/Multi-organ) |
| 1 | | | |
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| Director's Signature | Date |
|----------------------|------|
| Print Name | |

Part 3B, Section 3: Personnel - Additional Surgeon(s)

Complete this section of the application to describe surgeons involved in the program that are not designated as primary, but are credentialed by the transplant hospital to provide transplant services and independently manage the care of transplant patients, including performing the transplant operations and organ procurement procedures. Duplicate this section as needed.

1. Identify the additional transplant surgeon:

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:

b) Does the surgeon have FULL privileges at this hospital? (Check one)

| Yes | |
|-----|--|
| No | |

If the surgeon does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY): Explain the individual's current credentialing status, including any limitations on practice:

c) How much of the surgeon's professional time is spent on site at this hospital?

Percentage of professional time on site: Number of hours per week:

d) How much of the surgeon's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

| Facility Name | Туре | Location (City, State) | % Professional Time On Site |
|---------------|------|----------------------------------|--------------------------------|
| | | | |

e) List the surgeon's current board certification below. If board certification is pending, indicate the date the exam has been scheduled. If the surgeon has been recertified, use that date. Provide a copy of the certifications(s).

| Board Certification | Certification Effective Date/ Recertificatio n Date | Certification Valid Through Date | Certificate |
|----------------------------|---|-------------------------------------|-------------|
| Туре | (MM/DD/YY) | (MM/DD/YY) | Number |

Part 3C: Section 1 - Medical Personnel, Primary Physician

1. Identify the primary transplant physician:

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital: Date assumed role of primary physician:

b) Does the physician have FULL privileges at this hospital? (check one)

| Yes | |
|-----|--|
| No | |

If the physician does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY): Explain the individual's current credentialing status, including any limitations on practice:

c) How much of the physician's professional time is spent on site at this hospital?

Percentage of professional time on site: Number of hours per week:

d) How much of the physician's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

| Facility Name | Туре | Location (City, State) | % Professional Time On Site |
|---------------|------|---------------------------|--------------------------------|
| | | | |

e) List the physician's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the physician has been recertified, use that date. Provide a copy of the certifications(s). If the physician does not have current American or Canadian board certification, provide letters of recommendation requesting this exception and provide the plan for continuing education as described in the OPTN Bylaws.

| Board Certification Type | Certification Effective Date/ Recertificatio n Date (MM/DD/YY) | Certification Valid Through Date (MM/DD/YY) | Certificate Number |
|-----------------------------|---|--|--------------------|
| | | | |

f) Summarize how the physician's experience fulfills the membership criteria. Check the applicable pathway through which the physician will be proposed. Refer to the OPTN Bylaws for the necessary qualifications and more specific descriptions of the required supporting documents.

| Membership Criteria | | | |
|--|--|--|--|
| 12-Month Transplant Fellowship | | | |
| Clinical Experience Pathway (Post Fellowship) | | | |
| Pediatric Pathway | | | |
| Conditional Pathway | | | |

g) Transplant Experience (Post Fellowship)/Transplant Training (Fellowship):

List the name(s) of the transplant hospital(s), applicable dates, program director name(s), and the number of transplant patients for which the physician provided substantive patient care (pre-, peri- and post-operatively from the time of transplant).

| Training and | AST Approve | | a te DD/YY) | | | # PA Patients Follow | | |
|----------------------------------|--------------------------|-------|-----------------------|---------------------|---------------------|-----------------------------|------|------|
| Experience | d Progra m? Y/N | Start | End | Transplant Hospital | Program Director | Pre | Peri | Post |
| Fellowship Training | | | | | | | | |
| Experience Post Fellowship | | | | | | | | |

h) Transplant Training/Experience: List how the physician fulfills the criteria for participating as an observer of pancreas procurements and pancreas transplants. For procurements, the physician must have observed the evaluation, donation process, and management of the donors.

| Date From - To MM/DD/YY | Transplant Hospital | # of PA Transplants Observed | # of PA Procurements Observed |
|-------------------------------|---------------------|------------------------------------|-------------------------------------|
| | | | |
| | | | |

i) Describe in detail the proposed primary physician's level of involvement in **this** transplant program as well as **prior** training and experience.

| | Describe Level of Involvement in <u>This</u> Transplant Program | Describe Prior Training/Experience |
|----------------------|--|------------------------------------|
| Pre-Operative | | |
| Patient | | |
| Management | | |
| (Patients with | | |
| Diabetes Mellitus) | | |
| Recipient Selection | | |
| Donor Selection | | |
| Histocompatibility | | |
| and Tissue Typing | | |
| Immediate Post- | | |
| Operative and | | |
| Continuing Inpatient | | |
| Care | | |
| Post-Operative | | |
| Immunosuppressive | | |
| Therapy | | |
| Differential | | |
| Diagnosis of | | |
| Pancreatic | | |
| Dysfunction in the | | |
| Allograft Recipient | | |
| Histologic | | |
| Interpretation of | | |
| Allograft Biopsies | | |
| Interpretation of | | |
| Ancillary Tests for | | |
| Pancreatic | | |
| Dysfunction | | |
| Long-Term | | |
| Outpatient Follow- | | |
| up | | |
| Pediatric (if | | |
| applicable) | | |
| Coverage of Multiple | | |

| Transplant Hospitals (if applicable) | |
|--------------------------------------|--|
| Additional Information: | |

Table 5: Primary Physician - Recipient Log (Sample)

Complete a separate form for each transplant hospital.

| Organ: | |
|-------------------------------------|--|
| Name of proposed primary physician: | |
| Name of hospital where transplants | |
| were performed: | |
| Date range of physician's | |
| appointment/training: | |
| MM/DD/YY to MM/DD/YY | |

List cases in date order. Add rows as needed. Patient ID should <u>not</u> be name or Social Security <i>Number.

| vun | nber. | | Due | Devi | Deet | |
|------------------|-----------------------|-----------------------------|-----------------------|------------------------|------------------------|----------|
| # | Date of Transplant | Medical Record/OPTN ID # | Pre- Operativ e | Peri- Operativ e | Post- Operativ e | Comments |
| 1 | • | | | | | |
| 2 | | | | | | |
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| Director's Signature | Date |
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| Print Name | |

Table 6: Primary Physician - Observation Log (Sample)

| Organ: | |
|-------------------------------------|--|
| Name of proposed primary physician: | |

In the tables below, document the physician's participation as an observer in pancreas transplants and pancreas procurements. For procurements, the physician must have observed the evaluation, donation process, and management of the donors.

List cases in date order. Add rows as needed. Patient ID should <u>not</u> be name or Social <i>Security Number.

Transplants Observed

| # | Date of Transplant | Medical Record/ OPTN ID # | Hospital |
|---|--------------------|------------------------------|----------|
| 1 | | | |
| 2 | | | |
| 3 | | | |

Procurements Observed

| # | Date of Procurement | Medical Record/ OPTN ID # |
|---|------------------------|------------------------------|
| 1 | | |
| 2 | | |
| 3 | | |

Part 3C: Section 2 - Personnel, Additional Physician(s)

Complete this section of the application to describe physicians involved in the program that are not designated as primary, but are credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients. Duplicate this section as needed.

1. Identify the additional transplant physician:

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:

b) Does physician have FULL privileges at this hospital? (Check one)

| Yes | |
|-----|--|
| No | |

If the physician does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY): Explain the individual's current credentialing status, including any limitations on practice:

c) How much of the physician's professional time is spent on site at this hospital?

Percentage of professional time on site: Number of hours per week:

d) How much of the physician's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

| Facility Name | Туре | Location (City, State) | % Professional Time On Site |
|---------------|------|---------------------------|--------------------------------|
| | | | |

e) List the physician's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the physician has been recertified, use that date. Provide a copy of the certifications(s).

| Board Certification Type | Certification Effective Date/ Recertification Date (MM/DD/YY) | Certification Valid Through Date (MM/DD/YY) | Certificate Number |
|-----------------------------|--|--|-----------------------|
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Table 7: Certificate of Investigation

- 1. List all transplant surgeons and physicians currently involved in the program.
 - a) This hospital has conducted its own peer review of all surgeons and physicians listed below to ensure compliance with applicable OPTN Bylaws. Insert rows as needed.

b) If prior transgressions were identified has the hospital developed a plan to ensure that the improper conduct is not continued?

| Yes | |
|----------------|--|
| No | |
| Not Applicable | |

c) If yes, what steps are being taken to correct the prior improper conduct or to ensure the improper conduct is not repeated in this program? Provide a copy of the plan.

I certify that this review was performed for each named surgeon and physician according to the hospital's peer review procedures.

| Signature of Primary Surgeon | Date |
|--------------------------------|------|
| Print Name | |
| Signature of Primary Physician | Date |
| Print Name | |

Table 8: Program Coverage Plan

Provide a copy of the current Program Coverage Plan and answer the questions below. The program coverage plan must be signed by either the:

- a. OPTN/UNOS Representative;
- b. Program Director(s); or
- c. Primary Surgeon and the Primary Physician.

| | Ye s | N O |
|---|----------|--------|
| Is this a single surgeon program? | - | |
| Is this a single physician program? | | |
| If single surgeon or single physician, submit a copy of the pati | ent noti | ce or |
| the protocol for providing patient notification | | |
| Does this transplant program have transplant surgeon(s) | | |
| and physician(s) available 365 days a year, 24 hours a day, | | |
| 7 days a week to provide program coverage? | | |
| If the answer to the above question is "No," an explanation must that justifies why the current level of coverage should be accept MPSC. Please use the additional information section below. | | |
| Transplant programs shall provide patients with a written | | |
| summary of the Program Coverage Plan at the time of | | |
| listing and when there are any substantial changes in | | |
| program or personnel. Has this program developed a plan for notification? | | |
| Is a surgeon/physician available and able to be on the | | |
| hospital premises to address urgent patient issues? | | |
| Is a transplant surgeon readily available in a timely manner | | |
| to facilitate organ acceptance, procurement, and | | |
| implantation? | | |
| A transplant surgeon or transplant physician may not be on | | |
| call simultaneously for two transplant programs more than | | |
| 30 miles apart unless circumstances have been reviewed | | |
| and approved by the MPSC. Is this program requesting an | | |
| exemption? | | |
| If yes, provide explanation: | | |
| Unless exempted by the MPSC for specific causal reasons, the primary transplant surgeon/primary transplant | | |
| physician cannot be designated as the primary | | |
| surgeon/primary transplant physician at more than one | | |
| transplant hospital unless there are additional transplant | | |
| surgeons/transplant physicians at each of those facilities. | | |
| Is this program requesting an exemption? | | |
| | | |
| If yes, provide explanation: | | |
| Additional Information: | | |
| | | |